August 21, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 00N-1351/Use of the Term "Fresh" for Foods Processed with New Technologies

Dear Sir/Madam:

This comment is submitted by Stanislaus Food Products (Stanislaus) in response to the Food and Drug Administration's (FDA) solicitation of views from interested persons regarding whether the current regulatory definition of the term "fresh," 21 C.F.R. § 101.95, should be amended to permit the term's use in describing foods that have been subjected to new processing technologies to control pathogens. These new technologies include, but are not limited to, high pressure processing, pulsed electric field, pulsed light, submerged arc, and filtration. See generally Food Labeling: Use of the Term "Fresh" for Foods Processed with Alternative Nonthermal Technologies; Public Meeting, 65 Fed. Reg. 41,029 (July 3, 2000). For the reasons set forth below, Stanislaus strongly objects to any expansion of the current definition to permit unqualified use of the term "fresh" in labeling such processed foods.

Stanislaus produces thermally processed tomato products, such as tomato sauce, pasta sauce, and pizza sauce. Stanislaus' canned tomato products are processed in the traditional way, i.e., in one continuous process directly from fresh tomatoes. In contrast, the great majority of competitive tomato products are processed using a reduced cost, two-step manufacturing process, in which fresh tomatoes are first super concentrated into industrial grade concentrate and, at a later time and typically in a different location, the industrial concentrate is reconstituted with water to produce consumer-ready, finished tomato products. Tomato products produced by our traditional method (i.e., directly from fresh tomatoes) are clearly different from their remanufactured counterparts in organoleptic characteristics, including taste, flavor, and appearance. This being the case, we work diligently to enable consumers and other customers through labeling to make informed choices about the foods we offer. As our nation's leading manufacturer of

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00N-1351 C16

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quality"packed from fresh" tomato products, Stanislaus is vitally interested in the rules and interpretations of FDA regarding "fresh" claims. We actively have participated in and monitored the agency's rulemaking and compliance actions regarding "fresh" claims over the past decade.

Based upon our experience with FDA's development and application of its "fresh" rule, Stanislaus firmly believes that the current regulation should be maintained --without change -- and continue to govern use of unqualified "fresh" claims. The present regulation was a long time in the making, being finalized some 3½ years after FDA first was advised that Ragu Foods was marketing hermetically sealed pasta sauce prominently labeled as "Fresh Italian," even though the heat-processed contents were remanufactured from processed tomatoes, tomato paste and water. Since promulgation, the regulation has served well in addressing other misuses of the term, including Del Monte's improper use of the brand name "Fresh Cut" on a line of canned fruit and vegetable products. It properly embodies the salient features of what consumers expect in a food characterized as being "fresh."

The current regulation precludes misuse of the term "fresh" to imply that a food is unprocessed when, in fact, it has been processed (e.g., pasteurized). However, labeling use of the term is not subject to the regulatory definition in instances where use of "fresh" does not suggest or imply that the food is unprocessed or unpreserved (e.g., "fresh" used to described pasteurized whole milk, because consumers commonly understand that milk is nearly always pasteurized). 21 C.F.R. § 101.95. In contrast, use of "fresh" to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients is subject to the regulatory definition because such use implies that the food is not processed or preserved. Id. The regulatory definition provides:

> The term "fresh," when used on the label or in labeling of food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation. . . .

21 C.F.R. § 101.95(a).

FDA was prompted to initiate this reexamination of its regulation governing labeling use of "fresh" claims by representations from manufacturers that foods processed using the new technologies noted above maintain the same characteristics as unprocessed products. 65 Fed. Reg. at 41,030. However, these representations are not supported by the final report of the Institute of Food Technologists (IFT), entitled "Kinetics of Microbial Inactivation for Alternative Food

Processing Technologies" [hereinafter "IFT Final Report"], noted in the Federal Register. For example, IFT reports that high pressure processing results in changes in the appearance and structure of foods (IFT Final Report, High Pressure Processing, § 1.1.1), that pulsed electric field technology's effect on the chemical and nutritional properties of foods is not well understood (IFT Final Report, Pulsed Electric Fields, § 1); that high voltage arc discharge may result in chemical contamination with by-products and disintegration of food particles (IFT Final Report, High Voltage Arc Discharge, § 1); and that additional research is needed relative to these and other new technologies (IFT Final Report, Research Needs). The IFT Final Report also discloses that certain of the new technologies are not entirely nonthermal in application. This being the case, we believe IFT's final report militates against expanding the "fresh" definition to encompass foods processed using these new technologies. Importantly, we are unaware of any research demonstrating that "fresh" claims on such foods would be consistent with consumer expectations.

For these reasons, Stanislaus believes that FDA should not permit unqualified "fresh" claims on any product that is pasteurized or subjected to the new technologies. At the very least, it is premature to seriously contemplate amending the regulation in this regard.

While Stanislaus cannot support food labeling use of unqualified "fresh" claims that do not accord with the current regulatory definition, we strongly support continued FDA authorization of qualified fresh claims, including "packed/made from fresh [ingredient]." Such claims serve consumer/customer interests by allowing prominent and meaningful label differentiation of products made from fresh versus processed (e.g., concentrated, dehydrated) ingredients.

Finally, as FDA reexamines its "fresh" regulation, there remains a glaring omission, dating from 1993, in its implementation of the rule. In light of organoleptic differences between canned tomato products that are processed in the traditional way versus those products made from industrial-grade tomato concentrate, Stanislaus and other members of the California Packed From Fresh Tomatoes Coalition petitioned FDA in 1990 to require affirmative disclosure (e.g., "remanufactured" or "from concentrate") in labeling remanufactured tomato products so that consumers and other purchasers may easily distinguish between the different products. A number of national and regional consumer groups supported mandatory "from concentrate" disclosure for the remanufactured products. In the preamble to its "fresh" rule, FDA did not make a final decision on the Coalition's petition, but promised subsequently to take appropriate action. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2406 (Jan. 6, 1993). The time has come to take this promised action. FDA regulations already require prominent disclosure in labeling of similar foods made from

concentrated ingredients. E.g., 21 C.F.R. §§ 102.33(g)(1) (nonstandardized beverages that contain fruit or vegetable juice), 146.145(c) (orange juice from concentrate), 156.145(a)(2)(i)(B) (tomato juice from concentrate). Consumer/customer interests, regulatory consistency, and fairness demand that FDA also require "from concentrate" or a similar disclosure in labeling of remanufactured tomato products made from concentrated ingredients.

Stanislaus appreciates the opportunity to comment on this important matter, and urges FDA to take action in accordance with our comment. As in the past, we stand ready to assist the agency in implementing proper "fresh" claims regulation and enforcing compliance.

Respectfully submitted,

Robert Ilse

Robert Ilse
President